

Official Title: Scleral Depression Pain with Schocket Depressor and Cotton Tipped Applicator:
Depression Eye Pain Relief Evaluation Study (DEPRESS)

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Protocol Title: Depression Eye Pain Relief Evaluation Scale Study (DEPRESS)

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Background Information:

Scleral depression is a commonly used technique that enhances visualization of the peripheral retina and ora serrata. A patient is dilated with 1% tropicamide and 2.5% phenylephrine and anesthetized with 0.5% proparacaine to improve comfort and reduce the patient's need to blink. A 20 diopter lens and a binocular indirect ophthalmoscope are used to visualize the retina. Practitioners commonly use a flat double-ended metal scleral depressor such as the Schocket scleral depressor or a cotton-tip applicator and this preference has historically been based on physician's preference. The scleral depressor is placed perpendicularly on the scleral 5mm to 8mm posterior to the limbus as the patient looks in the opposite direction allowing a view of the peripheral retina and ora serrata. The level of patient comfort of metal scleral depressors and cotton tip applicators has never been established and that is what this study hopes to elucidate.

The risks to patients include discomfort and no harms have been documented as long as scleral depression is not used on patients that we will exclude from this study (below).

Population/Inclusion Criteria:

All patients at Kings County Hospital that will be undergoing scleral depression that are over 18 years of age and able to give consent. Scleral depression is indicated in patients with high myopia or peripheral retinal pathology that needs to be viewed or when patients have complaints of flashers and/or floaters and peripheral retinal detachments are needed to be ruled out. Monocular patients or patients not requiring scleral depression on both eyes will be included.

Exclusion Criteria:

Patients to be excluded include those under 18 years of age, unable to sign consent for themselves, pregnant patients. Scleral depression should not be done on patients with an open globe injury, hyphema, a scleral buckle, filtering bleb or recent ocular surgery within the last month.

Objectives/Purpose:

Determine the level of comfort that patients report using the Visual Analog pain Scale (VAS) after the scleral depression procedure using a flat double-ended metal scleral depressor or a cotton-tip applicator.

Trial Design:

This study will be designed as a single blind randomized control trial with crossover of the two scleral depression methods. The patient will be told that there are two separate devices for scleral depression but not shown each device prior to its selection. All patients will have their pupils dilated with 1% tropicamide and 2.5% phenylephrine 30 minutes prior to scleral depression and anesthetized with 0.5% proparacaine will be given immediately prior to scleral depression. Patient will be randomly assigned with a random number generator to determine the eye that will have scleral depression first, next the method of scleral depression will be randomly assigned. The contralateral eye will then have opposing scleral depression method utilized.

The VAS survey will be given to the patient immediately after the first eye is scleral depressed, then after the second eye is depressed they will be given the same VAS survey on a separate page so that they cannot see their first pain rating.

Secondary endpoints will include determining if associated medical problems that they have are associated with different levels of pain. The different VAS means will also be compared between the different practitioners and their level of training.

Statistics:

A T-test will be conducted to determine the significant between the means. A linear regression analysis and multiple regression analysis will be used to look for a correlation with the secondary outcomes.

Sample Size

A power analysis with the assumptions that the means will be 2 and 2.5 with a standard deviation of 2 and an alpha of 0.05 and a power of 95% requires a sample of 415. Thus, we plan to enroll 208 patients or 416 eyes.

Direct Access to Source Data Documents:

Joseph Raevis and the principle investigator will keep that data locked in a cabinet in the Kings County Hospital Eye clinic for the duration of the study.

References:

Dinardo A, Walling P. The Lost Arts of Optometry, Part One: A Refresher on Scleral Depression. Review of Optometry. August 15, 2013.